NOV 2 9 2002

SMDA 510(k) SUMMARY

K023767

UES-30 Electrosurgical Unit and its associated accessories

A. Submitter's Name, Address, Phone and Fax Numbers

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 34-3 Hirai Hinide-Machi, Nishitama-Gun , Tokyo 190-00182, Japan
Registration No.:	3003637092
Address, Phone and Fax Numbers Of R&D Endoscope Division:	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507,Japan TEL 81- 426-42-2891 FAX 81-426-46-5613

B. Name of Contact Person

Name: Address, Phone and Fax Numbers:	Laura Storms-Tyler Olympus America Inc. Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name:	UES-30 Electrosurgical Unit and its associated accessories
Common Name:	Electrosurgical Unit
Classification:	21 CFR 876.4300 Endoscopic electrosurgical unit and accessories, Class II 21 CFR 878.4400 Electrosurgical cutting and coagulation device and accessories, Class II
Predicate Device:	UES-20 (#K970184)

D. Description of the Device(s)

This instrument has been designed for general and endoscopic electrosurgery including polypectomy, TUR, and laparoscopy (cutting and coagulation) in conjunction with Olympus designated electrosurgical accessories, endoscopes (fiberscopes, videoscopes, and rigid scopes) applicable to electrosurgery, light source, and ancillary equipment.

E. Intended Use of the Device(s)

This instrument has been designed for general and endoscopic electrosurgery including polypectomy, TUR, and laparoscopy (cutting and coagulation) in conjunction with Olympus designated electrosurgical accessories, endoscopes (fiberscopes, videoscopes, and rigid scopes) applicable to electrosurgery, light source, and ancillary equipment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2002

The Olympus Optical Company
Laura Storms-Tyler
Director, Regulatory Affairs and Quality Assurance
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K023767
Trade/Device Name: UES-30 Electrosurgical Unit and its associated accessories
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 11, 2002
Received: November 12, 2002

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OLYMPUS

Indications for Use Statement

K023767

510(k) Number(if known): ~~Not assigned yet.~~

Device Name: UES-30 Electrosurgical Unit and its associated accessories

Indications for Use:

This instrument has been designed for general and endoscopic electrosurgery including polypectomy, TUR, and laparoscopy (cutting and coagulation) in conjunction with Olympus designated electrosurgical accessories, endoscopes (fiberscopes, videoscopes, and rigid scopes) applicable to electrosurgery, light source and ancillary equipment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Prescription 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023767